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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
ROBERTS, LEZAH	
ART UNIT	**PAPER NUMBER**
1614	

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11/28/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/772,781	GIN ET AL.	
	Examiner	Art Unit	
	Lezah W. Roberts	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 September 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-99* is/are pending in the application.

4a) Of the above claim(s) *9-11,14-22,27,31-45,49-54,58-71 and 75-99* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8, 12-13, 23-26, 28-29, 46-48, 55-57 and 72-74* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *A-B*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Election of Species/Restriction Requirement

Claims 9-11, 14-22, 27, 31-45, 49-54, 58-71 and 75-99 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention and species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on September 7, 2007.

Applicant's election with traverse of Group I, including claim 96, peppermint oil for the flavoring agent, ethylcellulose for the hydrophilic polymer, sucralose for the sweetener, lozenge for the dosage form and gum arabic and stearic acid for the additive in the reply filed on September 7, 2007 is acknowledged. The traversal is on the ground(s) that in the case of group I and VI they are closely related and substantially the same search would apply. This is not found persuasive because group VI is drawn toward a taste masking composition of a beneficial agent. Applicant has elected not to include a beneficial. Therefore even if the Examiner was to rejoin groups I and VI, claim 99 would be withdrawn as being drawn toward a non elected species.

The requirement is still deemed proper and is therefore made FINAL.

Claims

Claim Rejections - 35 USC § 112 - Indefiniteness

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2-4 and 23-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1) Claims 2-4 and 23 recite the limitation "the hydrophilic" in the first line. There is insufficient antecedent basis for this limitation in the claim.

2) Claims 23-24 recite the limitation "the weight ratio" in the first line. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103 - Obviousness

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

1) Claims 1-8, 12-13, 23-26, 28-29, 46-48, 55-57 and 72-74 are rejected under 35 U.S.C. 103(a) as being unpatentable over Friedman et al. (WO 99/06030, Already of Record).

Friedman et al. disclose slow release tablets comprising ethyl cellulose and an herbal medication. The tablets have dissolution times of up to 120 minutes (see Abstract) and may be formulated into lozenges (page 4, lines 23-25). Herbal medication encompasses herbal extracts, essential oils or combination of both. The polymeric material has a strong influence on the rate of release of medication from the tablets of the present invention. Ethyl cellulose is present from about 11 percent to about 53 percent of the composition. In regards a viscosity range from 1 to 120 cP as determined at 25°C using a 5% wt. aqueous solution of ethylcellulose, this is an inherent characteristic of commercially available ethylcellulose[1], encompassing claims 5-7.

[1] Dow, http://www.dow.com/dowexcipients/products/ethocel.hym, page 1, 1995.

Essential oils include peppermint oil. The essential oil and herbal extract are preferably present in a mixture of 1:4 to 1:30, essential oil to extract. They comprise 0.5 to 40 percent of the weight of the tablet (page 6, lines 7-11). Although the reference discloses the essential oils and extracts are used in mixture, it also discloses they may be used alone. It may be concluded that the essential oil may be present from 0.5 to 40% of the compositions. In regards to the mixture being a "wet matrix", in the presence of the essential oil or extract (when a liquid) it can be concluded the mixtures are wet. Furthermore when the ratio of ethyl cellulose to essential oil (when the essential oil is used as the sole herbal medication) is 11:40, the mixture has a liquid component. Colorants may be used in the compositions as well as sweetener such as sodium saccharin (Example 6), encompassing claims 26, 28-29, 46, 55-57 and 72. The compositions comprise polyethylene glycol as a release enhancer, encompassing claims 47 and 73. The polyethylene glycol may be PEG 300 to PEG 10,000. The reference differs from the instant claims insofar as it does not specifically disclose the mixture of ethyl cellulose and flavoring agent form a "wet matrix".

Normally, changes in result effective variables are not patentable where the difference involved is one of degree, not of kind; experimentation to find workable conditions generally involves the application of no more than routine skill in the art. In re Aller 105 USPQ 233, 235 (CCPA 1955). It would have been obvious to one of ordinary skill in the art to have adjusted the ratios of the essential oils and ethylcellulose motivated by the desire to obtain an oral dosage form of the desired consistency, as supported by cited precedent.

2) Claims 1-8, 12-13, 23-25, 30, 46-48, 72 and 73 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alderman et al. (US 4,528,125).

Alderman et al. disclose sustained release compositions comprising alkylcelluloses, preferably ethylcellulose and a fragrance. Ethyl cellulose is a polymer that is used to control the rate of release of and active agent (see Friedman et al. discussed above). The compositions may be formulated into lozenges (col. 6, lines 50-54). The flavorings include peppermint oil. Flavorings comprise 0.1 to 200 percent based on the weight of the cellulose ether (col. 5, lines 30-33). In regards to the wet matrix, based on the ratio of flavoring agent to cellulose ether, it may be concluded the amount of flavor oil would give the properties of a wet matrix as defined by Applicant. In regards to claims 5-7 reciting a viscosity range from 1 to 120 cP as determined at 25°C using a 5% wt. aqueous solution of ethylcellulose, this is an inherent characteristic of commercially available ethylcellulose (see footnote 1), encompassing claims 5-7. Pigments, fillers, preservatives and water soluble polymers may also be included in the compositions (col. 5, lines 34-68), encompassing claims 46 and 47. The reference differs from the instant claims insofar as it does not disclose the rate of release for the flavoring agent.

It would have been obvious to one of ordinary skill in the art to have adjusted the amount of ethyl cellulose in the compositions motivated by the desire to obtain the desired rate of release of the flavoring, as supported by cited precedent stated above. See In re Aller.

3) Claims 1-8, 12-13, 23-26, 28-29, 46-48, 55-57 and 72-74 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ventouras (US 6,183,775).

Ventouras discloses a controlled release lozenge having organoleptic properties. The lozenge comprises fillers including xylitol, mannitol and sorbitol (which are non sugar sweeteners); an insoluble film forming agent which is capable of forming an insoluble matrix including ethyl cellulose and a swellable polymer including xanthan gum and cellulose derivatives (see Abstract), encompassing claims 26, 28-29, 47, 55-57 and 73. The film forming agent comprises 0.5 to 30% of the total composition (col. 10, lines 32-35). The film former may be applied as an aqueous dispersion. The delivery of the active substance ranges from 15 minutes to 90 minutes (col. 1, lines 47-50). Flavoring includes peppermint oil (see formula 5). The flavoring comprises about 0.5% taken from Formula 5 which comprises peppermint oil. Auxiliaries are used in the compositions including aromas, sweeteners, colorants, buffering agents and preservatives. In regards a viscosity range from 1 to 120 cP as determined at 25°C using a 5% wt. aqueous solution of ethylcellulose, this is an inherent characteristic of commercially available ethylcellulose (see footnote 1), encompassing claims 5-7. The reference differs from the instant claims insofar as it does not disclose the compositions comprise a "wet matrix" of ethyl cellulose and a flavoring agent and a range for the amount of flavoring agent that may be added to the compositions.

It would have been obvious to one of ordinary skill in the art to have adjusted the ratios of the flavorings and ethylcellulose motivated by the desire to obtain an oral

dosage form of the desired consistency and the desired amount of flavoring, as supported by cited precedent above. See In re Aller.

Obvious-Type Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-8, 12-13, 23-26, 28-29, 46-48, 55-57 and 72-74 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7, 10-16 and 23 of copending Application No. 11/904420. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims are coextensive insofar as they both recite oral dosage forms, specifically lozenges that release an agent over a prolonged period of time

wherein the lozenge comprises an essential oil and a water insoluble polymer such as ethyl cellulose. The copending claims are genus claims insofar as the independent claim recites water insoluble polymer whereas the instant claims recite ethyl cellulose. The instant claims are genus claims insofar as they recite a dosage form in the independent claims and the copending claims recite lozenge.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-8, 12-13, 23-26, 28-29, 46-48, 55-57 and 72-74 are rejected.

Claims 9-11, 14-22, 27, 31-45, 49-54, 58-71 and 75-99 are withdrawn.

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lezah W. Roberts whose telephone number is 571-272-1071. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Art Unit 1614

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